

This Patient Group Direction (PGD) must only be used by registered health professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

Patient Group Direction

for the administration of CYCLOPENTOLATE 1% AND 0.5% EYE DROPS

by registered nurses and orthoptists to adult and paediatric patients in the Sussex Eye Hospital(SEH) A&E

Version number: 3

Change history

Version number	Change details	Date
1	Transfer of old PGD onto NICE/BSUH template	April 2016
2	Amendments by Janet Avery and Ann-Marie Goacher, Joy White	April 2016
3	Updated to new PGD template format and made more specific to A&E extended role. Information regarding orthoptists qualifications and training added.	March 2021

PGD development

Name	Job title and organisation	Signature	Date
Lead author	Ramavathi Veemarajan Nurse Manager for Pickford ward and A&E at SEH	Email approval	June 2021
Lead Doctor	Amanda Lewis Clinical Consultant Ophthalmologist SEH	Email approval	
Lead pharmacist	Ann Marie Goacher	Email approval	
Lead Clinician for area	Amanda Lewis	Email approval	
Representative of other professional group using PGD (User review)	Joy White Orthoptics Head of Service SEH	Email approval	

Organisational authorisations

University Hospitals Sussex authorises this PGD for use by the services or providers listed below:
Registered nurses and orthoptists at the Sussex Eye hospital (SEH)
Limitations to authorisation
Only registered nurses who have completed the additional training for the enhanced role in A&E

Name	Signature & Name	Date
Chair of PGD Group	Jo Pendlebury	July 21
Chief Pharmacist	Mike Cross	Oct 2021
Medicines Governance Group chair	Dr Michael Okorie	Oct 2021

Local enquiries regarding the use of this PGD may be directed to uhsussex.pgdgroup@nhs.net or PGD group chair.

Appendix 1 provides a practitioner authorisation sheet. Individual practitioners must be authorised by name to work to this PGD.

Training and competency of registered health professionals

	Requirements of registered health professionals working under the PGD
Qualifications and professional registration	Registered professional listed in the current PGD regulations with current NMC registration who have completed additional ophthalmic qualification. Nurses must complete 6 month in house training and assessment to achieve additional A&E enhanced role. OR orthoptists with current HCPC registration working at SEH who have completed in house training under supervision of senior orthoptists.
Additional requirements	The individual practitioner must be authorised by name, under the current version of this pgd before working according to it. And a working knowledge of adverse reactions to the medication used with the PGD and how to identify drug interactions.
Initial training	Register and complete PGD training module (certificate can be printed out as evidence) https://portal.e-lfh.org.uk/ (3 yearly) Has undertaken training appropriate to recognise and manage allergic/anaphylactic reactions and appropriate Trust resuscitation training. <ul style="list-style-type: none"> • Passed drug administration competency required by the Trust. • Has undertaken appropriate training on identifying the need for ocular mydriasis as indicated on this PGD. • Has undertaken additional training in Ophthalmic Accident and Emergency care to use the PGD under the extended role • Complete safe and secure handling of medicines training • Relevant IRIS / mandatory training
Competency assessment	The nurse/orthoptist must be authorised by name, under the current version of this PGD before you attempt to work according to it, by your Line Manager or Nominated Deputy and completed the eye drop administration competency The nurse will demonstrate clinical and professional competency using eye drop assessment tool (see ref) . Assessment by their line manager/ senior nurse. Orthoptists will complete training and assessment under supervision of senior orthoptists.
Continued training requirements	<ul style="list-style-type: none"> • Complete NICE Competency PGD Framework • PGD e-learning 3 yearly • Keep up to date with mandatory training • Maintain knowledge and skills within specialist area • PGD users will be responsible for collecting data and continuing to audit their practice

Clinical condition

Clinical condition or situation to which this PGD applies	<ul style="list-style-type: none"> - Dilation of the pupil(s) prior to retinal examination / refraction. - Pain control (by reducing ciliary spasm) following a corneal abrasion, corneal foreign body or minor corneal trauma.
Inclusion criteria	SEH patients within A&E requiring: <ul style="list-style-type: none"> - refraction - retinal examination - pain control as detailed above or who are excluded from Tropicamide eye drop PGD
Exclusion criteria	Known hypersensitivity to cyclopentolate hydrochloride or any other ingredient in this product. Presence of an iris clip lens
Cautions (including any relevant action to be taken)	Darkly pigmented irises are more resistant to cycloplegia and dilation. See comments in Dosage & Frequency below If anterior chamber lens(IOL) in place must consult duty doctor before administration
Arrangements for referral for medical advice	Refer to duty doctor/prescriber.
Action to be taken if patient excluded	<ul style="list-style-type: none"> • Consider assessing suitability for Tropicamide eye drop PGD as alternative option if for dilation. • Refer to attending Ophthalmologist if contra-indicated/ hypersensitive to all dilating drops. Seek alternative ways to control the pain for example if oral pain relief medications are required
Action to be taken if patient declines treatment	<ul style="list-style-type: none"> • Document refusal and action taken in patient's records. • Seek advice from Ophthalmologist.

Details of the medicine

Name, form and strength of medicine <i>Include ▼ for black triangle medicines</i>	Cyclopentolate eye drops minims 1% (single use dose units) Cyclopentolate eye drops minims 0.5% (single use does units)
Legal category	POM: Prescription only medicine
Indicate any off-label use (if relevant)	Use for children under 3 months is under PSD from duty doctor. Use of lower strength 0.5% in children rather than 1% is off label – supported as per evidence referenced below.
Route/method of administration	Topical to the eye
Dose and frequency	<i>Resistance to cycloplegia can occur in young children, in patients with dark skin and/or patients with dark irides, therefore, avoid excessive dosage by allowing sufficient time for full dilation /cycloplegia and by using 1% instead of 0.5 %</i> <ul style="list-style-type: none"> • Children 3months – 6 months: use Cyclopentolate 0.5%

	<ul style="list-style-type: none"> • Children 6 months and over: use Cyclopentolate 1% • Adults: use Cyclopentolate 1% <p><u>Note</u> SPC states use of 1% strength for children from 3 months to 12 years but practice at SEH has always been to use 0.5 % strength for 3 – 6 months of age and the desired effect has been achieved as per referenced evidence below.</p> <p><u>Refraction and Pre-Retinal examination</u></p> <ul style="list-style-type: none"> • Instil one drop into affected eye(s) 20 minutes prior to examination / refraction and one drop at 20 minutes intervals until sufficiently dilated / cycloplegia achieved. • Maximum 4 drops per eye. <p><u>Pain relief</u></p> <ul style="list-style-type: none"> • One stat dose to the affected eye. A further dose can be instilled every 15 minutes until a fixed dilated pupil is achieved. • Maximum 4 drops per eye
<p>Quantity to be administered and/or supplied</p>	<p>Single dose units used for administration.</p>
<p>Maximum or minimum treatment period</p>	<p>4 drops in total per eye</p>
<p>Adverse effects</p>	<p>A detailed list of adverse reactions is available in the SPC for each medicine, which are available from the electronic Medicines Compendium website: www.medicines.org.uk.</p> <p>Common Side Effects:</p> <p>(i) Local:</p> <ul style="list-style-type: none"> • transient stinging, sensitivity to light secondary to pupillary dilation, local irritation, acute angle-closure glaucoma • allergic reaction may include swelling and/or diffuse redness of eyelids or conjunctiva with lacrimation. Local effects may increase with increased concentration used. <p>Uncommon:</p> <p>(ii) Systemic:</p> <ul style="list-style-type: none"> • Systemic toxicity is uncommon but more likely to be seen in young children or very elderly patients, or in hyperaemia. • Rarely irregular heart rate, palpitations and arrhythmias, and ataxia. <p>(iii) Toxicity is usually transient and is manifest mainly by CNS disturbances: CNS disturbances may occur rarely in children. Any CNS disturbances are characterised by signs and symptoms of cerebellar dysfunction and visual and tactile hallucinations or seizures.</p> <p>Refer to these sources of information for full list:</p> <ul style="list-style-type: none"> • SPC at www.emc.medicines.org.uk • BNF at www.bnf.org

	<ul style="list-style-type: none"> • BNF for Children
Drug interactions	<p>Since systemic absorption can follow topical application, the possibility of interactions should be borne in mind. Punctal occlusion can be used to minimize systemic absorption.</p> <p>A detailed list of drug interactions is available in the SPC (summary of product which are available from the electronic Medicines Compendium website: www.medicines.org.uk)</p> <p>BNF/C also has drug interaction information</p>
Supplies	From RSCH Pharmacy
Storage	<p>Each Minims unit should be discarded after a single use.</p> <p>Store below 25°C.</p> <p>Do not freeze.</p> <p>Protect from light.</p>
Reporting procedure of adverse reactions	<p>Healthcare professionals and individuals/parents/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk</p>
Special considerations / additional information	<ul style="list-style-type: none"> • Allow 2 – 3 minutes gap between instillation of different drops. • Discard after single use
Records to be kept	<ul style="list-style-type: none"> • That valid informed consent was given. • Name of individual, address, date of birth and GP with whom the individual is registered • Drug history for patient including medical history • Diagnosis • Name of medication • Date of administration • Dose, form and route of administration • Laterality of eye in which the drops were administered • Member of staff who administered the medication • Quantity administered • Batch number and expiry date • Advice given, • details of any adverse drug reactions and actions taken • Details of any adverse drug reactions and actions taken including documentation in the patient's record, and sent to the GP • supplied via PGD <p>A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy. OR the patients should be identifiable in a timely manner for audit purposes.</p>

Written information to be given to patient or carer	<ul style="list-style-type: none"> • Verbal information only will be given if single dose administered.
Follow-up advice to be given to patient or carer	<ul style="list-style-type: none"> • Drops will sting and enlarge the pupil. • Cause blurred vision, difficulty in focusing, discomfort in bright light / daylight. • Do not to drive or engage in other hazardous activities (including climbing ladders and scaffolding) unless vision is clear. • Effect of dilation may last 4 – 8 hours. Complete recovery from the effects of Cyclopentolate eye drops may take up to 24 hours, or longer in patients with deeply pigmented eyes. • Remove contact lenses for the duration of the treatment

Audit

Plan for audit , It is essential for PGD renewal that audits have occurred.	Incorporate into SEH audit plan in line with PGD group requirements. Audited using approved PGD audit tool.
Frequency	Every 3 years (in line with PGD process – 2 years after PGD approval)
Nominated lead to manage audit	Ramavathi Veemarajan Nurse Manager for Pickford ward and A&E at SEH

Key references

<ul style="list-style-type: none"> • SPC at www.emc.medicines.org.uk (Accessed 20/4/21) • BNF at www.bnf.org (Accessed 20/4/21) • BNF for Children <p>Evidence-Based Clinical Practice Guideline: Comprehensive Paediatric Eye and Vision Examination American Optometric Association. Accessed 06/2021 at https://www.aoa.org/AOA/Documents/Practice%20Management/Clinical%20Guidelines/EBO%20Guidelines/Comprehensive%20Paediatric%20Eye%20and%20Vision%20Exam.pdf</p>
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Appendix 1 Health professionals' agreement to practise

PGD Title...CYCLOPENTOLATE 1% AND 0.5% EYE DROPS.....

Practitioner, by signing this patient group direction you are indicating that you agree to its contents and that you will work within it.

Patient group directions do not remove inherent professional obligations or accountability.

It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct

Name of health professional	Role	Signature	Date

Authorising manager

I confirm that the practitioners named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of University Hospitals Sussex for the above named health care professionals who have signed the PGD to work under it.

Name	Role	Signature	Date